

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q76104

Hiroshi TAKEYAMA, et al.

Appln. No.: 10/611,902

Group Art Unit: 1614

Confirmation No.: 8672

Examiner: James Anderson

Filed: July 3, 2003

For: ANTI-TUMOR AGENT

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on
September 13, 2007:

REMARKS

During the Interview, the following was discussed:

1. Brief description of exhibits or demonstration:

None.

2. Identification of claims discussed:

Claims 1 -3 and 16 -17 were discussed.

3. Identification of art discussed:

None.

4. Identification of principal proposed amendments:

The proposed amendments were discussed orally over the telephone and pertained to claim 1 as set forth in the Remarks section.

5. Brief Identification of principal arguments:

Claim Rejection - 35 U.S.C. § 112

Claims 1-3 and 16-17 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action alleged that the phrase “a dose of 1 mg - 50 mg/tumor volume (cm^3)” was unclear.

The undersigned discussed with Examiner Anderson a proposal to amend independent claim 1 to recite: “a dose of 1 mg - 50 mg/cm^3 of tumor volume” to obviate the rejection. Examiner Anderson agreed that the rejection would be obviated in view of the proposed amendment.

Next, Applicant's attorney discussed with Examiner Anderson the second rejection under section 112, second paragraph, with respect to the term “dose.” Previous Examiner Graffeo had asserted that the second recitation of “dose” in claim 1 was allegedly indefinite because it was asserted to be unclear whether dose corresponds to $1 \text{ mg}/\text{cm}^3$ - $50 \text{ mg}/\text{cm}^3$ recited previously or whether there is another dose that corresponds to necrotic tumor cells.

Examiner Anderson appeared to take a different view from Examiner Graffeo with respect to the understanding of the second recitation of “dose.” Examiner Anderson indicated that he did not intend to maintain this rejection.

Claim Rejections Under 35 U.S.C. § 103(a)

At page 3 of the Office Action, claims 1-3 and 16-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,284,786 to Casciari et al. (hereinafter “Casciari et al.”) in view of “The anti-tumor effect to stomach cancer by benzyl alcohol,” Meeting of Japan Surgical Society on April 12-14, 2000, issued on March 2000, PP-1457

(hereafter "Reference PP-1457") in light of Stedman's Medical Dictionary, 25th Edition (1990), p. 1026-1027 (cited for definitions).

Applicant's position is that (1) Casciari et al. and reference PP-1456 do not teach or suggest the combination of ascorbic acid and benzyl alcohol or the combination dosages of ascorbic acid and benzyl alcohol; (2) the Declaration Under 37 C.F.R. § 1.132 of Dr. Takeyama filed April 14, 2006 is sufficient to obviate the *prima facie* obvious rejection; and (3) claim 1 has been amended to further recite that "the vitamin C can be used in a range of 0.1 to 10 times 1 part of BA by weight."

With respect to the Declaration, the Examiner initially stated that the evidence was not persuasive because the evidence presented related to *in vitro* testing. The Examiner's attention was directed to Cross v. Jizuka, which held that *in vitro* test data is sufficient and acceptable as being predictive of *in vivo* activity. Examiner Anderson stated that he will consider the case law.

Further, the Examiner stated that the evidence provided in the Declaration is not commensurate in scope with claim 1, because claim 1 is directed to stomach, breast, large bowel, thyroid gland or pancreatic tumor cells, while the § 1.132 Declaration evidence is limited to stomach tumors. Examiner Anderson suggested that he likely would consider claim 1 to be allowable if claim 1 was further amended to limit the tumors to stomach tumors. Alternatively, Applicant may wish to consider submitting supplemental evidence of unexpected superior results with respect to breast, large bowel, thyroid gland, and/or pancreatic tumor cells.

6. Indication of other pertinent matters discussed:

None.

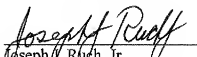
7. Results of Interview:

The Examiner will consider Applicant's argument upon receipt of the Amendment.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,


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Date: October 15, 2007